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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 09/688,756      | 10/16/2000  | Fatih M. Uckun       | 12152.76USD1        | 1604             |

23552 7590 12/27/2002

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| EXAMINER |
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LIU, HONG

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| ART UNIT | PAPER NUMBER |
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1624

DATE MAILED: 12/27/2002

12

Please find below and/or attached an Office communication concerning this application or proceeding.

**Advisory Action**

Application No.

09/688,756

Applicant(s)

UCKUN ET AL.

Examiner

Hong Liu

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--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 25 November 2002 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE. Therefore, further action by the applicant is required to avoid abandonment of this application. A proper reply to a final rejection under 37 CFR 1.113 may only be either: (1) a timely filed amendment which places the application in condition for allowance; (2) a timely filed Notice of Appeal (with appeal fee); or (3) a timely filed Request for Continued Examination (RCE) in compliance with 37 CFR 1.114.

**PERIOD FOR REPLY [check either a) or b)]**

- a) ☒ The period for reply expires 3 months from the mailing date of the final rejection.
- b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection. ONLY CHECK THIS BOX WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

1. ☐ A Notice of Appeal was filed on \_\_\_\_\_. Appellant's Brief must be filed within the period set forth in 37 CFR 1.192(a), or any extension thereof (37 CFR 1.191(d)), to avoid dismissal of the appeal.
2. ☐ The proposed amendment(s) will not be entered because:
- (a) ☐ they raise new issues that would require further consideration and/or search (see NOTE below);
- (b) ☐ they raise the issue of new matter (see Note below);
- (c) ☒ they are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
- (d) ☐ they present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: \_\_\_\_\_.

3. ☐ Applicant's reply has overcome the following rejection(s): \_\_\_\_\_.
4. ☐ Newly proposed or amended claim(s) \_\_\_\_\_ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
5. ☐ The a) ☐ affidavit, b) ☐ exhibit, or c) ☐ request for reconsideration has been considered but does NOT place the application in condition for allowance because: \_\_\_\_\_.
6. ☐ The affidavit or exhibit will NOT be considered because it is not directed SOLELY to issues which were newly raised by the Examiner in the final rejection.
7. ☐ For purposes of Appeal, the proposed amendment(s) a) ☐ will not be entered or b) ☐ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.

The status of the claim(s) is (or will be) as follows:

Claim(s) allowed: \_\_\_\_\_.

Claim(s) objected to: \_\_\_\_\_.

Claim(s) rejected: 30-35.

Claim(s) withdrawn from consideration: \_\_\_\_\_.

8. ☐ The proposed drawing correction filed on \_\_\_\_\_ is a) ☐ approved or b) ☐ disapproved by the Examiner.
9. ☐ Note the attached Information Disclosure Statement(s) (PTO-1449) Paper No(s). \_\_\_\_\_.
10. ☐ Other: \_\_\_\_\_

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***Attachment to the Advisory Action***

***Status of the Application***

Applicant response filed on November 25, 2002 in paper No. 11 is hereby acknowledged.

***Rejection Maintained***

Applicants' arguments were fully considered but were not found persuasive. Therefore, rejections to claims 30, 32, 33, and 35 under 35 U.S.C. 102(b) and claims 30-35 under 35 U.S.C. 103(a) are maintained for reasons already made of record notwithstanding applicants' traverse.

***Claim Rejections - 35 USC § 103***

Rejection to claims 30-35 under 35 U.S.C. 103(a) as being unpatentable over Myers et al. (WO 95/15758) is maintained for the reasons set forth in the office action mailed in paper No. 7 and 9. Applicants first argue that the mode of action of the reference compounds is to inhibit CSF-1R receptor tyrosine whereas the mode of action of the instantly claimed compounds is inhibition of JAK-3, a non-receptor tyrosine kinase. The distinction drawn by the applicants, although persuasive, is not particularly relevant in the nonobviousness analysis because the claims are not directed to subject matter of inhibition of JAK-3 or CSR-1R. Rather, the claims are drawn to a method of treating inflammation using the 6, 7-alkoxy quinazoline compounds. Therefore, the issue is whether the inflammation caused by CSF-1R abnormality is so different

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from the JAK-3-mediated inflammation that the reference compounds are only good at inhibiting autoimmune inflammation and the instantly claimed compounds are only effective in treating UVB-radiation induced inflammation. From what applicants' description of these two types of inflammation, it appears that both UVB radiation caused inflammation and autoimmune inflammation involve activated macrophage and elevated levels of cytokines. If the quinazoline derivatives are effective in modulating the activated macrophage such that the production of the pro-inflammatory cytokines could be reduced, one would expect that the quinazoline compounds could be used to treat autoimmune inflammation and inflammation involving JAK-3 because of the similarity of the underlying mechanisms of these two types of inflammation. Absent experimental evidence showing that the reference compounds are indeed effective in treating autoimmune inflammation but not JAK-3-associated inflammation, applicants' conclusion that "compounds that might inhibit inflammation in the one may not inhibit inflammation in the other" does not seem to stand on a firm ground.

In view of applicants' amendment not overcoming the art rejection, this application is not placed in condition of allowance.

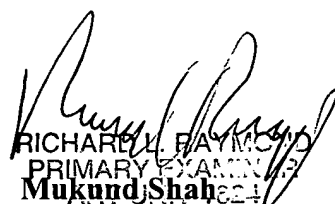
### ***Claim Rejections - 35 USC § 102***

Claims 30, 32, 33, and 35 remain rejected under 35 U.S.C. 102(b) as being unpatentable over Myers et al. (WO 95/15758) for the same reasons given above.

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Any inquiry concerning this communication should be directed to Examiner Hong Liu whose telephone number is (703) 306-5814. If attempts to reach the examiner by the phone are unsuccessful, the examiner's supervisor, Mukund Shah can be reached at (703) 308-4716. The fax phone number for this group is (703) 308-4734 for "unofficial" purposes and the actual number for official business is (703) 308-4556. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose number is (703) 308-1235.

Hong Liu  
December 17, 2002

  
RICHARD L. RAYMOND  
PRIMARY EXAMINER  
**Mukund Shah**  
**Supervisory Patent Examiner**  
**Art Unit 1624**